510(k) Summary

JAN 0 8 2013

New Device: Mega 5.5 Spine System

1. Submitter and US Official Correspondent

Submitter:	BK MEDITECH CO., LTD.
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US Official Correspondent:	Shin Kuk Yoo, Consultant LSK BioPartners, Inc. 8 East Broadway, Suite 611 Salt Lake City, UT 84111, USA Telephone No.: 714-313-7442 Fax No.: 801-303-7455 Email: skyoo@LSKBioPartners.com

2. DeviceInformation

Proprietary/Trade Name:	MEGA 5.5 Spine System
Common/Usual Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Pedicle screw spinal system
Regulation Number:	21 CFR 888.3070
Device Class:	Class II
Product Code:	MNH, MNI

3. Identification of Legally Marketed Predicate Devices

Substantial equivalence for the MEGA 5.5 Spine System is based in its similarities in indication for use, design features, operational principles and material composition when compared to the predicate device cleared under the following submissions:

- Mega Spine System (K072436, BK MEDITECH Co., Ltd.)
- OPTIMA™ Spinal System (K031585, U&I Corporation, America)
- DELTA, Spinal Fusion System (K071857, Jemo Spine, LLC)
- Moss Miami Spinal System Polyaxial Screws (K030383, DePuy AcroMed, Inc)

4. DescriptionofDevice

The MEGA5.5 Spine System is a top-loading multiple component, posterior spinal fixation systems which consists of pedicle screws (mono, long-arm, multi-axial and multi-axial long-arm screw), rods, locking bolt, and a transverse linking mechanism (cross-link). The MEGA5.5 Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The MEGA5.5 Spine System implant components are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136. Various sizes of these implants are available. Specialized instruments are also available for the application and removal of the MEGA5.5 Spine System.

5. IndicationsforUse

The Mega 5.5 Spine System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft, having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Mega 5.5 Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

6. PerformanceTesting

Mechanical testing as listed in ATTACHMENT II that was conducted in accordance with ASTM F 1717 demonstrates equivalence to the above predicate devices. This testing included static and dynamic compression bending, static tension bending, and static torsion. The subject spinal implant system is therefore substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

BK Meditech Company, Limited
% LSK BioPartners, Incorporated
Mr. Shin Kuk Yoo
8 East Broadway, Suite 611
Salt Lake City, Utah 84111

Letter dated: January 8, 2013

Re: K123476
Trade/Device Name: MEGA 5.5 Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: November 9, 2012
Received: November 13, 2012

Dear Mr. Shin Kuk Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K123476

Device Name: Mega 5.5 Spine System

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123476